REMARKS

Applicants have cancelled Claims 42-50, and 57-81. Applicants maintain that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the cancelled claim in this or another patent application. Applicants have amended Claims 36, 39-41, 51, and 54-56 and have added new Claims 88-108. The amendments to the claims add no new matter and are fully supported by the specification. In particular, support for the amendments can be found, for example, on page 28, line 19 - page 29, line14; page 67, line 19 - page 69, line 14; page 69, lines 22-24, and elsewhere throughout the specification and claims as originally filed.

Upon entry of the foregoing amendments, Claims 36, 38-41, 51, 53-56 and 82-108 are pending and presented for examination. Applicants respond below to the specific rejections raised by the Examiner in the final Office Action mailed October 12, 2006. For the reasons set forth below, Applicants respectfully traverse and request notification that the pending claims have been allowed.

Rejection Under 35 U.S.C. § 112, first paragraph - Enablement

The Examiner has maintained the rejection of Claims 36-87 as allegedly not being described in the specification in such a way as to enable one skilled in the art to make and use the full scope of the claimed invention. According to the Examiner, the specification is "enabling for inducing an enhanced antibodies [*sic*] response against HCV NS3 by using the full length polynucleotide of SEQ ID NO: 16. . . with an optimal concentration of rabvairin [*sic*] or the polynucleotide encoding the polypeptide of SEQ ID NO:17." *Office Action* at 2-3. However, the Examiner argues that the specification "does not reasonably provide enablement for using few base pairs of nucleic acids of said polynucleotide, such as 24 mers or 30 mers of SEQ ID NO: 16 in combination with any concentration of rabivirin [*sic*] to produce the same biological effect." *Id.* at 4.

During a personal interview between the undersigned, Examiner Li, and Supervisor Campell held May 16, 2006, it was agreed that "112 2nd and 112 1st issues were removed in view of applicants [*sic*] demonstrations of disclosues [*sic*] in the specification and declaration showing CTL epitopes of NS3/4A identified or accepted in the state of the art prior to the application was [*sic*] filed," (*Interview Summary*, mailed June 22, 2006). Nevertheless, the

Examiner now maintains that the Declaration is not persuasive. According to the Examiner, neither the Declaration nor specification provides "sufficient evidence to support that every short nucleotides [*sic*] of SEQ ID NO: 16 is such an immunogenic epitope, when it is used with rabivirin [*sic*] at any concentration, it is able to elicit an enhanced humoral and cellular immune responses [*sic*] at any time of the treatment with a subject as claims drafted [*sic*]." *Office Action* at 3. Further, According to the Examiner, Hultgren et al. (*J. Gen. Virol.* 1998, 79:2381-2391)("Hultgren") demonstrates the unpredictability of ribavirin, which "is generally considered as an immunosuppressive agent or immunomodulator." *Office Action* at 3. The Examiner concludes that the skilled artisan would have to undertake undue experimentation to make and use the full scope of the invention.

Applicants maintain their position taken in the personal interview on May 16, 2006, and agreed upon by Examiner Li and Supervisor Campell discussed above, *i.e.*, that the specification and the Declaration of Dr. Sällberg obviate the rejections under 35 U.S.C. § 112, first paragraph raised by the Examiner in the Office Action mailed February 27, 2006. Nevertheless, solely in the interest of advancing the prosecution of the instant case, Applicants have cancelled Claims 42-50 and 57-81. Applicants have also amended Claims 36 and 51 to recite methods of increasing the titer of antibodies specific to *hepatitis* viral antigens *consisting essentially of* providing, *in a single administration*, an immunogenic composition.

Claims 36, 38-41, 51, 53-56 and 82-108 recite methods of increasing the production of hepatitis viral antigen specific IgG antibodies or enhancing a T cell response to a hepatitis viral antigen in a subject in need thereof "*consisting essentially of* identifying a subject in need of [an increase in titer of IgG antibodies or an improvement in a T cell response]. . . and providing, *in a single administration*, an immunogenic composition that comprises an effective amount of ribavirin and a nucleic acid encoding hepatitis viral antigen to said subject." As set forth in Section 2111.03 of the M.P.E.P., the transitional phrase "consisting essentially of" has a well-established meaning which occupies a middle ground between claims that recite the transitional phrase "consisting of," which exclude all steps (or materials) other than those recited in the claim, and claims that recite the transitional phrase "comprising," which do not exclude additional, unrecited steps (or materials). The transitional phrase "consisting essentially of" limits the scope of a claim by excluding additional materials or steps that materially affect the

basic and novel characteristics of the invention. *Atlas Pander Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 224 (Fed. Cir. 1998).

Applicants maintain that in the instant case, the basic and novel characteristics of Claims 36, 38-41, 51, 53-56 and 82-108 relate to enhancing the production of hepatitis-specific IgG antibodies or enhancing T cell responses to a hepatitis viral antigen in a subject that has been identified as one in need thereof. Accordingly, any steps that materially affect the enhancement of the production of hepatitis-specific IgG antibodies or the improvement of T cell response to hepatitis antigens in the identified subject are excluded from the claims. As such, contrary to the Examiner's assertions, the claims do not encompass "any concentration[] of rabavirin [*sic*] regardless of duration of the treatment." *Office Action* at 4. The specification as originally filed enables the skilled artisan to practice the full scope of the claimed methods without undue experimentation.

Applicants therefore respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Double Patenting

The Examiner has provisionally rejected Claims 36-40 as allegedly being unpatentably obvious over Claim 1 of co-pending U.S. Patent Application No. 11/411,493. Applicants submit herewith a Terminal Disclaimer, thereby addressing and overcoming the Examiner's provisional rejection of the claims. Applicants respectfully request that the Examiner withdraw the provisional double patenting rejection.

CONCLUSION

The undersigned has made a good-faith effort to respond to the Office Action and to place the claims in condition for allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicants' attorney, Eric S. Furman, Ph.D., at (619) 687-8643 (direct line) to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 2/7/07

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